



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Nancy Malsich
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9/12/03
Date of Deposit

Applicant: Maruyama, et al.)	
Serial No.: 08/852,020)	Group Art Unit: 1636
Filed: May 6, 1997)	Examiner: G. Leffers, Jr.
For: LAMBDROID BACTERIOPHAGE)	
VECTORS FOR EXPRESSION OF)	Our Ref.: TSRI 432.0 D1
FOREIGN PROTEINS)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response to Office Action

AMENDMENT

Dear Sir:

This Amendment is filed in response to the Office Action of March 13, 2003. Enclosed herewith is a Petition for a three-month extension of time and a check in the amount of \$930.00 to cover the cost of that extension.

Remarks/Arguments begin on page 2 of this paper.

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REMARKS/ARGUMENTS

Claims 57-60 are currently pending.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 57-60 under the first paragraph of 35 U.S.C. § 112 as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserts that the specification does not contain a description of where, within the coding sequence for head or tail proteins (other than pV) one would insert the sequences for the linker polypeptide and the desired preselected polypeptide. The Examiner further asserts that there is no description as to which portions of head or tail proteins might be dispensable for morphogenesis. The Examiner finally asserts that there are no relevant examples in the specification of such a fusion construct for any of the potential head or tail polypeptides other than pV. Applicants respectfully argue against this rejection for the reasons of record as well as for the reasons set forth below.

To fulfill the written description requirement of the first paragraph of 35 U.S.C. § 112, the patent specification must only describe an invention in sufficient detail that a skilled artisan can conclude that the inventor invented the claimed invention. An Applicant complies with this requirement by describing the invention with all its claimed limitations by using descriptive means, such as words, that set forth the claimed invention.

The Examiner's assertions regarding coding sequence locations, anchor matrix polypeptide portions dispensable for morphogenesis and the lack of relevant examples are not relevant to the written description requirement as they are not limitations of the claims. Indeed the specification of the instant application contains virtual *ipsis verbis* support for the pending claim language. Further, with regard to head or tail proteins, the specification, at numerous locations, provides explicit lists of appropriate head or tail proteins that can be used in the instant invention. Applicants, therefore, respectfully submit that this rejection by the Examiner is not well taken and respectfully request that this rejection be withdrawn.

The Examiner has also rejected claims 57-60 under the first paragraph of 35 U.S.C. § 112 for an alleged lack of enablement. In support of this allegation, the Examiner asserts that because (a) the specification contains only an example of using the pV polypeptide, and (b) of the asserted unpredictability of the art (as evidenced by referenced art such as Moody), the specification fails to teach one of ordinary skill in the art how to make and use the claimed invention. Applicants respectfully argue against this rejection for the reasons of record as well as for the reasons set forth below.

Applicants respectfully submit that the reliance of the Examiner on Moody is immaterial and irrelevant. The Examiner relies on Moody as teaching a view of phage assembly that describes how different types of phage have tackled the problem of encapsulating the phage genetic material in a protective structure that itself relies on a minimum of genetic information

to encode the head structure. The Examiner also credits Moody as teaching that assembly of a phage head is a complex process that is liable to errors. Finally, the Examiner relies on Moody as teaching that phage head assembly is a complex process involving multiple protein-protein interactions that change during a process and involving several different types of proteins. Thus, the Examiner seems to be relying on Moody to teach the unpredictability of using particular anchor matrix proteins to form a phage particle displaying the proteins on its surface.

The Examiner goes on to assert that the specification of the instant application is further evidence of the unpredictability of the claimed invention. The Examiner relies on those portions of the specification dealing with the number of copies of pV and the expression of only a few copies of the fusion polypeptide even though higher levels of expression could have been expected.

First, the number of fusion polypeptides expressed on the surface of the phage is not relevant to the presently claimed invention as a minimum number of expressed polypeptides is not a claimed limitation. Further, the specification describes in explicit detail how anchor matrix proteins, other than pV, existing in greater copy numbers (e.g., pD), might result in a greater number of expressed polypeptides.

In a previous amendment, Applicants submitted a publication by Mikawa, et al. as evidence of enablement for other head or tail proteins. The Examiner correctly points out that the publication of Mikawa is after the priority date of the instant application. The Examiner states that it is not clear that the methods used by Mikawa are commensurate with teachings of the

instant disclosure. The Examiner goes on to cite isolated phrases from Mikawa that allegedly support this assertion.

In this regard, the Examiner has failed to recognize that Mikawa, et al. use virtually the identical procedure for expression of a phage using the pD protein as that taught in the instant specification using the pV protein. Mikawa explicitly teaches, on pages 25-28, the use of vector λ foo to express fusion polypeptides using pD. This is the same vector disclosed in the instant application for use of the pV protein. Applicants respectfully submit that this provides proof that the teachings of the instant application enable one of ordinary skill in the art to make and use the claimed invention. Further, given that pV is a tail protein and that pD is a head protein, this evidence provides explicit support that the teachings of the instant specification enable the claimed invention for both head or tail proteins.

In view of the above, Applicants respectfully request withdrawal of this rejection.

SUMMARY

In view of the above, Applicants respectfully submit that the claims are now in a condition of allowance. An early notification to that effect is hereby earnestly solicited.

Serial No.: 08/852,020

TSRI 432.0 D1

Respectfully submitted,

9-12-03

DATE

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